

REMARKS

Applicant appreciates the cooperation of Examiner Hoffman during the personal interview of December 8, 2006. Although no formal agreement was reached at the interview, the Examiner did indicate that arguments presented at that time and reproduced below “appear to overcome some of the prior art,” as memorialized in the Interview Summary. It is Applicant’s understanding that this statement applies at least to DE 32 44 680 to Clarenz and U.S. Patent No. 5,571,105 to Gundolf, as well as possibly to U.S. Patent No. 5,993,452 to Vanderwalle and U.S. Patent No. 3,469,573 to Florio.

Claims 13-21, 23-28, and 30-41 are pending in this application.

Applicant has amended independent claims 13, 24 and 31 above to recite that the bone-contacting enlargements have peripheries circumferentially surrounding the flexible cable. The added feature was previously recited in claims 22 and 29, now canceled. The amendment was presented to the Examiner during the personal interview. Applicant notes that the subject matter of the independent claims, as amended, was previously of record vis-à-vis dependent claims 22 and 29. Accordingly, should another Office Action issue, Applicant respectfully submits that the action should remain non-final.

Applicant respectfully requests approval and entry of the claim amendments.

Claim Rejections -- 35 U.S.C. § 102

Claims 13, 16-18, 22-24, 26-33, 35, 36, 38, and 40 have been rejected under 35 U.S.C. § 102(b) as being anticipated by DE 32 44 680 to Clarenz.

Applicant respectfully traverses this rejection.

As discussed during the personal interview, Clarenz does not disclose a surgical instrument having bone-contacting enlargements with peripheries circumferentially surrounding a flexible cable. As best shown in Fig. 1 of Clarenz, the alleged bone-contacting enlargements 18 are formed on only one side of the alleged cable 2. Unlike the claimed invention, the alleged bone-contacting enlargements 18 do not surround the alleged cable 2. This distinction was pointed out to and acknowledged by the Examiner at the personal interview. It was further pointed out that Clarenz's alleged cable 2 is actually a flat belt, and as such would have been unlikely to twist during passage around an injured bone. Accordingly, there would not have been motivation to modify Clarenz to extend its alleged bone-contacting enlargements 18 to surround the belt 2.

For these reasons, Applicant respectfully submits that the Section 102(b) rejection of independent claims 13, 24, and 31 over Clarenz is misplaced, and respectfully requests reconsideration and withdrawal of the rejection. Applicant further respectfully submits that the remaining rejected claims, which are in dependent format and incorporate the distinguishing features of the independent claims from which they depend, are patentable for the same reasons and for the additional reason that the added subject matter thereof is neither disclosed in nor reasonably suggested by the art.

Claims 13, 14, 16, 18, 21-26, 28-33, and 36-41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,571,105 to Gundolf.

Applicant respectfully traverses this rejection.

As discussed during the personal interview, Gundolf does not disclose a surgical instrument having bone-contacting enlargements with peripheries circumferentially surrounding a flexible cable. As best shown in Fig. 1 of Gundolf, the alleged bone-

contacting enlargement 21 is formed on only one side of the alleged cable 10. Unlike the claimed invention, the alleged bone-contacting enlargements 21 do not surround the alleged cable 10. This distinction was pointed out to and acknowledged by the Examiner at the personal interview. It was further pointed out that Gundolf's alleged cable 10 is actually a flat belt or strap, and as such would have been unlikely to twist during passage around an injured bone. Further, the alleged bone-contacting enlargements 21 are spikes. Accordingly, there would not have been motivation to modify Gundolf to modify its spikes 21 into a member that circumferentially surrounds the strap 10.

For these reasons, Applicant respectfully submits that the Section 102(b) rejection of independent claims 13, 24, and 31 over Gundolf is misplaced, and respectfully requests reconsideration and withdrawal of the rejection. Applicant further respectfully submits that the remaining rejected claims, which are in dependent format and incorporate the distinguishing features of the independent claims from which they depend, are patentable for the same reasons and for the additional reason that the added subject matter thereof is neither disclosed in nor reasonably suggested by the art.

Accordingly, withdrawal of the Section 102 rejections of claims 13, 14, 16-18, 21-33, and 35-41 is respectfully requested.

Claim Rejections -- 35 U.S.C. § 103

Claims 14, 15, 19, 20, 21, and 25 have been rejected as being unpatentable over Clarenz.

Applicant respectfully traverses this rejection.

Claims 14, 15, 19, 20, and 21 depend from claim 13. Claim 25 depends from claim 24. As explained in detail above, Clarenz fails to disclose or reasonably suggest forming its alleged bone-contacting enlargements 18 to surround its alleged cable 2, as recited in claims 13 and 14. The Examiner's allegations regarding general skill of a worker in the art with respect to known materials does not negate this conclusion. For this reason, Applicant respectfully submits that the Section 103(a) rejection of claims 14, 15, 19, 20, 21, and 25 is misplaced, and respectfully requests withdrawal of the same.

Claims 15, 19, and 20 have been rejected as being unpatentable over Gundolf.

Applicant respectfully traverses this rejection.

Claims 15, 19, and 20 depend from claim 13. As explained in detail above, Gundolf fails to disclose or reasonably suggest forming its alleged bone-contacting enlargements 21 to surround its alleged cable 10, as recited in claim 13. The Examiner's allegations regarding general skill of a worker in the art with respect to known materials does not negate this conclusion. For this reason, Applicant respectfully submits that the Section 103(a) rejection of claims 14, 15, 19, 20, 21, and 25 is misplaced, and respectfully requests withdrawal of the same.

Claims 13-23 and 36-39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,993,452 to Vanderwalle in view of U.S. Patent No. 3,469,573 to Florio.

Applicant respectfully traverses this rejection.

Vanderwalle discloses a cerclage system including a wire 18 that encircles a bone and a jacket 28 for supporting the wire 18 with respect to the bone. The jacket 28 is made of a material which is resorbed into the patient's body. (Column 2, lines 1-3)

Vanderwalle explains that development of its invention focused on overcoming the problems caused by the tight fit of cerclages around a bone. This tight fit potentially can induce necrosis in the areas of the bone contacted by the cerclage band. Necrosis is caused by insufficient blood flow to the bone tissue. (Column 1, lines 34-38) Another problem that Vanderwalle attributed to this tight fit was that bones tend to continue to grow around the cerclage band and incorporate the band, thereby complicating removal of the band. (Column 1, lines 41-44)

To overcome these problems, Vanderwalle developed a cerclage system designed to provide a tight constrictive fit as the bone heals, but then thereafter loosen. In order to accomplish this object, Vanderwalle made the jacket 28 of its cerclage system out of a resorbable material. The material is resorbed by the patient's body. Because the jacket 28 spaces the wire 18 from the bone, resorption of the jacket 28 loosens the wire 18 about the bone so that the wire 18 no longer secures the bone. The loosening of the wire is claimed to be responsible for allowing normal blood flow past the wire 18. Inadvertent long-term damage to the bone is thereby avoided. Also, absorption of the jacket 28 and loosening of the wire 18 are purported to prevent the bone from growing around and incorporating the wire 18, thereby facilitating removal of the wire 18 in a subsequent procedure if desired. (Column 3, lines 39-52)

The Examiner acknowledges in the Office Action that Vanderwalle does not disclose "the bone-contacting enlargement being permanent and comprising a metal or a high molecular weight polymer, specifically polyethylene." (Page 8, lines 16-18) To overcome this deficiency, the Examiner points to Florio, which the Examiner alleges to disclose permanent bone-contacting enlargements.

Applicant respectfully submits that a person having ordinary skill in the art at the time the invention was made would not have been motivated to combine Vanderwalle and Florio in the manner suggest by the Examiner, absent hindsight.

Vanderwalle attributes the problems of necrosis and bone incorporation of the cerclage to the tight fitting contact of the cerclage against the bone. Vanderwalle teaches that the cerclage must be loosened to avoid these problems. Vanderwalle repeated states that it is the loosening of the cerclage that alleviates the blood flow restriction and avoids the bone from growing around and incorporating the cerclage. Column 3, lines 41-43, for example, state that “it is now beneficial for the permanently assembled cerclage wire 18 loop to loosen to avoid inadvertent long-term damage to the bone.” Column 4, lines 27-29 similarly state that “the cerclage cable 58 loop needs to loosen from the femur 56 to avoid inadvertent long-term damage to the femur 56.” The loosening of the cerclage cable due to resorption of the jacket is described as “advantageous.” (Column 5, lines 36-38)

Applicant respectfully submits that the Examiner’s proposed modification of replacing Vanderwalle’s resorbable material with a permanent material runs contrary to the express teachings of Vanderwalle. As modified, Vanderwalle’s jacket 28 would not be resorbed into the body, and the wire 18 would not be loosened. Vanderwalle makes clear that loosening of the wire 18 is not only “advantageous,” but the crux of its invention and the aspect responsible for overcoming the problems of the prior art. Vanderwalle is specifically focused on replacing permanent material with non-permanent, resorbable material in order to cause loosening of the cerclage. To ignore

these express teachings would contradict the spirit and scope of Vanderwalle and go against its teachings.

For these reasons, Applicant respectfully submits that the Section 103 rejection is misplaced and respectfully requests withdrawal of the same.

Additionally, Applicant respectfully submits that a person having ordinary skill in the art at the time the invention was made would not have had a reasonable expectation success in combining the two patents. Vanderwalle defines success as providing a device that both prevents necrosis and avoids bone growth around the cerclage. Florio does not disclose or reasonably suggest that its device will address this latter problem. To the contrary, Florio states that its clamping device makes “provision for the growth and development of soft tissue, such as fibrous tissue, blood vessels, etc., to grow in and through the device.” (Column 2, lines 1-4) Because Florio expressly acknowledges that its devices does not overcome both of the problems addressed by Vanderwalle, i.e., does not prevent incorporation of the cerclage device, the artisan of ordinary skill would not have been motivated to make the combination.

Furthermore, even if it would have been obvious to combine Vanderwalle with Florio, which Applicant refutes for the reasons advanced above, Applicant respectfully submits that the combination of the two patents would not render the claims obvious. The combination proposed by the Examiner filters down to modifying Vanderwalle’s cerclage system to include Florio’s alleged permanent bone-contacting enlargements. However, Florio’s alleged permanent bone-contacting enlargements do not have peripheries circumferentially surrounding a flexible cable, as recited in the amended

claims. For these additional reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 24-30, 38, and 39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Vanderwalle in view of Florio further in view of U.S. Patent No. 6,595,994 to Kipela et al.

Applicant respectfully traverses this rejection.

Applicant has specified above the various deficiencies of Vanderwalle and Florio, taken alone or in combination vis-à-vis the independent claims. The Kipela '994 patent does not overcome these deficiencies. Rather, the Kipela '994 patent has been cited by the Examiner for its disclosure of a tensioning device.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection of claims 24-30, 38, and 39.

Claims 31-35, 40, and 41 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Vanderwalle in view of Florio further in view of U.S. Patent No. 5,414,658 to Kipela et al.

Applicant respectfully traverses this rejection.

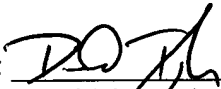
Applicant has specified above the various deficiencies of Vanderwalle and Florio, taken alone or in combination vis-à-vis the independent claims. The Kipela '658 patent does not overcome these deficiencies. Rather, the Kipela '658 patent has been cited by the Examiner for its disclosure of a connecting device.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection of claims 31-35, 40, and 41.

Applicant has filed a petition for one-month extension and extension fee herewith.

If the petition and/or any fee due in connection with the filing of this response are missing or deficient, please charge Deposit Account No. 50-0548 and accept this paper as a petition for extension, if necessary.

Respectfully submitted,

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